

**REMARKS**

Claims 1, 7, 9, 11-13 and new claims 16-17 are pending in this application for the Examiner's review and consideration upon entry of this paper. Claims 1, 7, 9, and 11-13 have been amended to more clearly recite the claimed invention. Claims 2-5 and 14-15 have been cancelled without prejudice. Applicants reserve the right to file one or more divisional or continuation applications to any canceled subject matter. New claims 16-17 have been added. Support for the amendment of claims 1, 7, and 9 can be found at paragraph [0027] to [0044] of the specification. Support for the amendment of claims 11-13 can be found at paragraph [0027] to [0044] and [0049] to [0050] of the specification. Support for the new claim 16-17 can be found at paragraph [0039] of the specification. Support for the new claim 17 can be found at paragraph [0039] of the specification. No new matter has been added by the amendments.

**I. The Objections to the Specification**

The Office Action alleges that the amendment filed on August 28, 2003 is objected to under 35 U.S.C. § 132(a) because it introduces new matter into the disclosure. According to the office action:

Although the application is a divisional of 09/207,056, the added material which is not supported by the original disclosure in the '056 application which was added to the instant specification is as follows: the terms "about" and "around", the value "5.35 kcal/g", and the ranges recited in claims 7 and 9.

Applicants respectfully submit that they have amended the value "5.35 kcal/g" to "5.36 kcal/g" in claims 12 and 13. Support for this amendment can be found in the specification at page 20, paragraph [0050].

The terms "about" and "around" of value "5.36 kcal/g" in claims 12 and 13, Applicants bring to the Examiner's attention that the value "5.36 kcal/g" is the estimated kilocalories per gram of unknown oil. (See specification, page 20, paragraph [0051]). Therefore the estimated value supports the terms "about" and "around" as recited in claims 12-13. Furthermore, Applicants have amended the ranges in claims 7 and 9 to recite "24.7% to 34.7%" and "19.7% to

60.0%,” respectively. Support for the amended ranges in claims 7 and 9 can be found in Examples 1-12. Additionally, Applicants has removed the terms “about” and “around” from claims 7 and 9.

Accordingly, Applicants respectfully submit that claims 1, 7, 9, 11-13, and 16-17 are fully supported by the specification of the current pending application.

## **II. The Objections to the Claims**

Claim 2 is objected to on page 4 of the Office Action as allegedly being confusing to recite the Abbreviation SFI. Applicants respectfully submit that Claim 2 has been canceled and Claim 16 is amended to recite the phrase “solid fat index (SFI)” to clarify the abbreviation.

Claim 11 is objected to on page 4 of the Office Action as allegedly being inconsistent with the recitation of “the thermostable lipase enzyme”. Applicants respectfully submit that the term “enzyme” has been deleted from Claim 11.

Accordingly, Applicants respectfully submit that the objections to Claims 2 and 11 should be withdrawn.

## **III. The Rejections Under 35 U.S.C. § 112, First Paragraph**

### **A. The Enablement Rejection Should be Withdrawn**

Claims 1-5, 7, 9, and 12-15 are rejected on pages 4-7 under 35 U.S.C. § 112, first paragraph, as allegedly being based on a disclosure which is not enabling. According to the Office Action, none of the compositions to the extent claimed is recited, supported, or unambiguously exemplified by the disclosure such that the disclosure does not reasonably teach or make obvious to one of skill how to make and use the claimed composition.

Applicants respectfully submit that they have amended claims 1, 7, 9, and 11-13 and canceled claims 2-5 and 14-15.

The invention relates to a reduced calorie fat and a process for the preparation of a reduced calorie fat. Independent claim 1 is drawn to a structured fat composition comprising of behenic acid, oleic acid and linoleic acid as major fatty acids, and palmitic acid, stearic acid, arachidic acid and lignoceric acid as minor fatty acids. Independent claim 11 is drawn to a method of

manufacturing a structured fat. Independent claim 17 is drawn to a specific structured fat comprising of 34.7% behenic acid, 17.1% oleic acid, 35.2% linoleic acid, 4.9% palmitic acid, 4.8% stearic acid, 1.7% arachidic acid and 1.6% lignoceric acid.

The specification discloses twelve examples to synthesize structured fat compositions including these fatty acids as disclosed in claims 1 and 17. (*See, for example*, specification, paragraph [0027] to [0043]). These examples also illustrate a process to synthesize fatty acids as recited in Claim 11 including inter-esterifying one or more edible oils with ethyl behenate in the presence of a thermostable lipase at a temperature in the range of 25 °C to 150 °C. As acknowledged in the Office Action at page 6, the relative skill of those in the art is high. Therefore, the disclosure of the specification is sufficient to enable a person with ordinary skill in the art to make and use the invention as defined in independent claims 1, 11 and 17.

Furthermore, Applicants have amended the ranges in claims 7 and 9 to “from 5.1% to 52.5%” and “from 19.7% to 60.0%,” respectively. Support for the amendment can be found at paragraph [0027] to [0044] in the specification. The examples disclose the content of behenic acid as 29.8%, 52.5%, 32.1%, 36%, 34.7%, 16.5%, 5.1%, 14.2%, 19.3%, 24.7%, 22.0% and the content of linoleic acid as 44.6%, 24.8%, 33.7%, 37.7%, 35.2%, 47.9%, 60.0%, 52.3%, 48.5%, 51.9%, 51.5%, 19.7%. The data disclosed in the examples are commensurate with the scope of the range recited in claims 7 and 9. The Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” In *re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. In *re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a “reasonable correlation” to the scope of the claims.

Applicants submit that based on the specification and knowledge of one of ordinary skill in the art, the claimed invention is enabled based on the disclosure of the specification.

Accordingly, Applicants respectfully submit that the rejection to claims 1, 7, 9, 11-13 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

**B. Written Description**

The Office Action further rejects claims 1-5, 7, 9 and 11-15 on pages 7-9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Office Action, “% total molecular species” in claim 4 is not supported by the original disclosure. The terms “about 24.7% to 34.7%”, “about 33.7% to 51.5%”, and “around 5.35 Kcal/g” render the claims broader scope than supported by the specification.

Applicants submit that claim 4 has been canceled rendering the rejection to claim 4 moot.

Applicants respectfully submit that they have amended the value “5.35 kcal/g” to “5.36 kcal/g” in claims 12 and 13. Support for this amendment can be found in the specification at page 20, paragraph [0050]. The terms “about” and “around” in claims 12 and 13 are supported by the specification. Applicants direct the Examiner’s attention page 20, which discloses that the value “5.36 kcal/g” is the estimated Kilocalories per gram of unknown oil. (See specification, page 20, paragraph [0051]). Therefore, the estimated value in the specification supports the terms “about” and “around” as recited in claims 12-13.

Finally, Applicants have amended the ranges in claims 7 and 9 to “from 5.1% to 52.5%” and “from 19.7% to 60.0%” respectively. Support for the amendment can be found at paragraph [0027] to [0044] in the specification.

Claim 11 has been rejected on page 9 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description. Specifically, the office action alleges the recitation of “from sources including *M. miehei*” expands the scope of the claims to the entire genus of 1,3-lipases. Applicants respectfully submit that they have amended Claim 11 to recite “selected from *M. miehei*” to clarify the scope of the claim.

Accordingly, Applicants respectfully submit that the rejection of claims 1, 7, 9, and 11-13 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

**IV. The Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-5, 7, 9, and 11-15 are rejected on pages 9-10 of the Office Action under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention.

Applicants respectfully submit that they have cancelled claims 14-15 and amended claims 1, 7, 9, 11-13. Support for the amendment of claims 1, 7, and 9 can be found at paragraph. [0027] to [0044] in the specification. Support for the amendment of claims 11-13 can be found at paragraph [0027] to [0044] and [0049] to [0050] in the specification. Cancellation of claims 14-15 renders the rejections of claims 14-15 moot.

Applicants respectfully submit that the rejection of claims 5, 7, 9, and 11-15 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. According to the Office Action, it is unclear in Claim 4 whether “Effective Carbon Number” or “TAG” is the controlling parameter in defining the HPLC-characterized composition and whether the composition corresponds to the composition of Claim 1.

Applicants respectfully submit that they have cancelled Claim 4 thereby rendering the rejection to Claim 4 moot.

The Office Action further rejects Claims 12-15 on pages 12 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. According to the Office Action, it is unclear as to the terms “delivery” and “about 5.35 Kcal/g.”

Applicants have amended the value “5.35 kcal/g” to “5.36 kcal/g” in claims 12 and 13. Support for this amendment can be found in the specification at page 20, paragraph [0050]. As for the terms “about” and “around” in claims 12 and 13, Applicants bring to the Examiner’s attention that the value “5.36 kcal/g” is the estimated Kilocalories per gram of unknown oil (*See* specification, page 20, paragraph [0051]). Therefore, the estimated value in the specification

supports the terms “about” and “around” as recited in claims 12-13. As for the term “delivery,” it is the fatty acids that constitutes the delivery and delivers the calories. (See specification, page 13, paragraph [0040] to [0058]).

Therefore, Applicants respectfully submit that the rejection of claims 1, 7, 9, and 11-15 under 35 U.S.C. § 112, second paragraph, should be reconsidered and withdrawn.

**V. The Rejections Under 35 U.S.C. § 103**

Claim 11 is rejected on pages 13-14 of the Office Action under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,654,018 to CAIN et al. (“CAIN”). According to the office action,

[S]ince Cain teaches a composition which contains the structured fat(triacylglyceride) BOB which, through produced by a different method, Cain still meets the minimum requirement of the instantly claimed composition. It would have been obvious to use the method of Cain because Cain teaches a structured fat having 1,3-behenic fatty acid group and a 2-oleic fatty acid group comprising the triacylglyceride.

Applicants respectfully submit that they have amended Claim 11 to thereby overcoming the rejection. CAIN discloses a process for the preparation of fats comprising SUS- and SSU-triglycerides high in behenic acid. (See, Abstract of U.S. Patent 5,654,018). CAIN’s process includes (1) an oil high in erucic acid is selected; (2) the selected oil is subjected to an enzymatic hydrolysis using an enzyme specific for the production of diglyceride; (3) a diglyceride rich in di-erucin is separated from the crude reaction product (1); (4) the di-erucin is catalytically hydrogenated to dibehenic; (5) the dibehenic is esterified enzymatically in the presence of free fatty acids; (6) a mixture of triglycerides is separated from the crude reaction product (5). (See U.S. Patent No. 5,654,018, column 2, lines 60-67, column 3, lines 1-6). The enzyme used in CAIN’s process step (2) is a lipase, preferably selected from the group of *Pseudomonas cepacia*, *Geotrichum candidum* and *Candida rugosa*. The enzyme used in CAIN’s process, step (5) is a lipase that does not react with long chain fatty acids, preferably *Candida Rugosa*. As

acknowledged in the Office Action on page 13, the instant invention discloses a different method from CAIN's to produce fatty acids.

The instant invention recites a process comprising mixing alkyl behenate with one or more edible oils in the presence of a thermostable lipase, *Mucor miehei*, at a temperature in the range of about 25 °C to 150 °C for at least about 0.5 hours, followed by recovering the structured fat. The instant invention utilizes alkyl behenate rather than diglyceride rich in dierucin to react with edible oils in the presence of *Mucor miehei* in one pot. CAIN does not teach or suggest either one-pot synthesis of fatty acids or the use of enzyme *Mucor miehei* as defined in Claim 11. On the contrary, a person with ordinary skill in the art would not be motivated to explore the one-pot inter-esterification reaction based on the teachings of CAIN because conversion of an oil to diglyderide and further to dibehenic acid is crucial in the process. Additionally, CAIN is limited to the reaction from only one oil, not one or more edible oils with alkyl behenate in the presence of a thermostable lipase at a temperature in the range of about 25 °C to 150 °C. Accordingly, Applicants respectfully submit that the rejection of Claim 11 under 35 U.S.C. § 103(a) should be reconsidered and withdrawn.

Claims 1-5, 7, 9, and 11-15 are rejected on pages 14-17 of the Office Action under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,116,745 to MAZUR *et al.* ("MAZUR"). According to the Office Action:

Mazur teaches representative examples of forming a 2-position monoglyceride from a triacylglycerol (TAG) (e.g. Example I) and the representative example of forming diacylglycerides (DAG) and subsequently TAGs from the 2-position reagent (e.g. Examples II, IV and V). Since Mazur teaches a finite number of fatty acid residues suitable for substitution into the product, and because selection of a plant oil such as sunflower oil would further narrow this selection to even-numbered fatty acids, it would have been obvious to make a composition having the instantly recited (individual) triglycerides based on the teachings of Mazur.

Applicants respectfully traverse the rejection for at least the following reasons.

Mazur discloses a process for the preparation of 1,2-diacylglycerol or 2,3-diacylglycerol using a primary lower alkyl alcohol selected from the group consisting of methanol, the primary

butanols and the primary pentanols and 2-butanol, an aqueous buffer system and a 1,3-lipase. Mazur's process includes lipase assisted hydrolysis of triglycerides to obtain 2-acyl glycerides, which in turn is esterified with fatty acid anhydrides in presence of 1,3-specific lipase to obtain 1,2-diacylglycerol or 2,3-diacylglycerol (*See* Abstract of U.S. Patent No. 5,116,745 to MAZUR et al. ).

Mazur does not teach or suggest the structured fat composition comprising behenic acid, oleic acid and linoleic acid as major fatty acids and palmitic acid, stearic acid, arachidic acid and lignoceric acid as minor fatty acids as recited by the claims in the current invention. Additionally, Mazur does not teach or suggest any method to obtain the claimed composition of behenic acid, oleic acid and linoleic acid as major fatty acids and palmitic acid, stearic acid, arachidic acid and lignoceric acid as minor fatty acids in the current invention. In fact, Mazur teaches away from the instant claims in disclosing the method to produce the claimed composition. First, as stated in Mazur, the process starts with acylation of the monoglyceride in the presence of an enzyme with an acid anhydride to 1,2-diglycerides or 2,3-diglycerides, followed by the esterification of diglycerides with acid chlorides or acid anhydrides to produce triglycerides. (*See* column 7, lines 25-30 of U.S. Patent No. 5,116,745). This process is completely different from the process recites in the instant invention which comprises inter-esterifying one or more edible oils with lower-alkyl behenate or low-alkyl behenic acid in the presence of an enzyme. The utilization of an ester or an acid in the esterification reaction is a significant advantage of the current invention and constitutes a more efficient approach to generating the reduced calorie fat.

Second, Mazur teaches that stereospecific triglycerides of the type MLL/MLM can be used as reduced calorie fats to partially or totally replace normal triglyceride fat in any fat-containing food composition. (*See* column 7, lines 55-60 of U.S. Patent No. 5,116,745). Mazur defines M as medium chain saturated fatty acid residue having 6-10 carbon atoms and L as a long chain saturated fatty acid residue having 14 to 24 carbon atoms. (*See* column 4, lines 8-10 and lines 22-24, and column 7, lines 55-60 of U.S. Patent No. 5,116,745). According to Mazur, at least one long chain saturated fatty acid and at least one medium chain saturated fatty acid is required to form the reduced calorie fats. However, the components recited by the claims of the



current invention are only long chain fatty acids, behenic acid ( $C_{22}H_{44}O_2$ ), palmitic acid ( $C_{16}H_{32}O_2$ ), linoleic acid ( $C_{18}H_{32}O_2$ ), oleic acid ( $C_{18}H_{34}O_2$ ), and stearic acid ( $C_{18}H_{36}O_2$ ). A person with ordinary skill in the art would therefore not be motivated to explore the combination of only long chain fatty acid to produce the reduced calorie fats based on the teaching of Mazur since Mazur teaches that a medium chain fatty acid is critical in the combination. Furthermore, behenic acid ( $C_{22}H_{44}O_2$ ), palmitic acid ( $C_{16}H_{32}O_2$ ) and stearic acid ( $C_{18}H_{36}O_2$ ) are unsaturated fatty acids. A person with ordinary skill in the art based on the disclosure of Mazur would not include them in the production of the reduced calorie fats since they are not qualified as saturated fatty acids as required by Mazur.

For at least these reasons, the teaching of Mazur would not disclose or suggest the claimed invention to one of ordinary skill in the art since it does not describe every component disclosed in the claimed invention. Even assuming *arguendo* one of ordinary skill in the art was motivated to try the method disclosed by Mazur, one of ordinary skill in the art would still not arrive at the claimed invention, as Mazur requires the presence of medium saturated chain fatty acids. Applicant respectfully request that the rejection of claims 1, 7, 9, and 11-13 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

## **VII. Conclusions**

It is respectfully submitted that the rejections to the claims have been overcome. Should the Examiner disagree, Applicant respectfully requests a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issues payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

Dated: **May 20, 2008**  
Morgan, Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
202-739-3000

Respectfully submitted,  
**Morgan, Lewis & Bockius-LLP**

  
Dean L. Fanelli (Reg. No. 48,907)